Reg. Std.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 1

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 055947-EUP-RL. Dicamba in or on corn. Evaluation of EUP for new formulation (SAN 1275H). MRID#s 432311-01 to -09. Barcode D203816. CBTS# 13814.

FROM: G.F. Kramer Ph.D., Chemist
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Health Effects Division (7509C)

THRU: P.V. Errico, Section Head
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Health Effects Division (7509C)

TO: Robert Taylor, Product Manager
Karen Hicks, Team 25 Reviewer
Registration Division (7505C)

Sandoz has petitioned for an EUP to evaluate a new microencapsulated formulation of dicamba for use in preemergent and early postemergent applications to corn. Tolerances are established for the combined residues of dicamba (3,6-dichloro-*o*-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-*o*-anisic acid in or on corn grain at 0.5 ppm, corn fodder at 0.5 ppm and corn forage at 0.5 ppm [40CFR§180.227(a)].

RECOMMENDATIONS

CBTS recommends against the proposed EUP for microencapsulated dicamba on corn for reasons detailed in conclusion 1.

CONCLUSIONS

1. A sample label for SAN 1275H has not been provided. Without this label, CBTS is unable to determine whether the field trials represent the use pattern which will be employed in the EUP program. The registrant will be required to submit an acceptable label for SAN 1275H before CBTS can recommend in favor of this EUP request.

2a. Five field corn trials were conducted in the states of IA, IL, IN, KS and NC. Analysis of the field samples showed that the maximum residues (total of dicamba and 5-OH dicamba) were 0.12 ppm in silage and 0.049 ppm in stover. Residues in excess of 0.01 ppm were not observed in any treated grain sample or in any of the nontreated control samples. Over tolerance residues resulting from the use of RH 1275H were reported in corn forage. However, these "forage" samples do not meet the Agencys' definition of forage: "whole aerial portion of the plant at late dough/early dent stage (black ring stage for corn only" (Table II, June 1994). As now defined, the silage samples are the RAC covered by the forage tolerance. Early season corn forage is not considered to be a significant animal feed item. Thus, all residues in corn RACs in this study were well below the established tolerances of 0.5 ppm. These data are adequate to support this EUP request.

2b. The registration of a new microencapsulated formulation will require a full set of corn field trials, as defined in the "*EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances, 6/2/94.*" For field corn, a total of 20 trials are required, conducted in Region 1- 1 trial, Region 2- 1 trial, Region 5- 17 trials and Region 6- 1 trial. The appropriate modes of application (i.e., preplant, at-plant, preemergence and postemergence) should be represented as detailed in the Field Trial Document. Also, two independent samples from each plot should be collected and analyzed and the minimum spray volume should be represented. The RACs sampled should be forage (as defined in Table II, June 1994), grain and fodder (stover).

3a. The maximum storage period for the samples from the field trials was 174 days from sampling to analysis. As these samples were stored for a relatively short period of time, CBTS concludes that storage stability is not an issue for this EUP.

3b. However, for the permanent registration request, further evidence of the storage stability of dicamba and 5-OH dicamba residues in corn RACs will be required. The registrant reports that a new 3-year storage stability study is in progress in conjunction with reregistration. CBTS also notes that some of the samples in this study were stored for up to 1.5 months between extraction and analysis. If the samples for the permanent registration request are stored as extracts, then data

demonstrating the stability of dicamba and 5-OH dicamba residues in corn RAC extracts will be required.

DETAILED CONSIDERATIONS

Formulation

The new formulation, SAN 1275H, is a liquid containing 37% a.i. and 2.5 lbs. a.i. (sodium salt) per gallon. Dicamba is microencapsulated in order to provide a slow release of a.i. following preemergent and early postemergent applications to corn.

Note: The registrant has also submitted product chemistry data for the end use product (MRID#s 432311-01 to -08). These data requirements are under the purview of RD and are thus not reviewed herein.

EUP Program

The proposed EUP program will cover the 1995 and 1996 growing seasons. Trials (200) will be conducted on 4000 acres in 13 different states. The maximum amount of a.i. applied will be a total of 2000 lbs./season.

Proposed Use

A sample label for SAN 1275H has not been provided. Without this label, CBTS is unable to determine whether the field trials represent the use pattern which will be used in the EUP program. The registrant will be required to submit an acceptable label for SAN 1275H before CBTS can recommend in favor of this EUP request.

Magnitude of Residue- Plants

Submitted with this petition:

> Crop Residue Study with SAN-1275H Dicamba Formulation on Corn MRID# 432311-09

Five field corn trials were conducted in the states of IA, IL, IN, KS and NC. Together, these states represented 42% of the U.S. corn acreage in 1991 (*Agricultural Statistics*, 1992). Each site

consisted of five plots- four treated and one untreated. Four different treatment regimens were employed: Treatment 1- a single preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A; Treatment 2- a preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A plus an early postemergence application of the DMA salt of dicamba at a rate of 0.5 lbs. ai/A; Treatment 3- a preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A plus a mid post emergence application of SAN 1275H at a rate of 0.25 lbs. ai/A; and Treatment 4- a single early postemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A. Preemergence applications were made within 24 hours of planting; early postemergence treatments, at the 4-5 leaf stage; and mid postemergence treatments, at the 6-8 leaf stage. Application volumes were 15-20 gal/A. Forage samples were taken 59-69 days after planting; silage samples were taken at the black layer stage, 110-142 days after planting; and grain and stover samples were taken at maturity, 125-159 days after planting. Samples were shipped to MVTL Laboratories, MN for analysis. The samples were analyzed by method AM-0691B, which has previously been reviewed and approved by CBTS for enforcing dicamba tolerances in corn (Memo, F. Griffith 11/4/88). Problems with interferants in some samples necessitated minor revisions; i.e., addition of a C-18 cleanup column and use of an alternative GC column. The method was validated in corn RACs at 0.01 ppm (the LOQ) and 0.10 ppm. The average recovery was 83 ± 13% (n=20) for dicamba and 89 ± 14% (n=20) for 5-OH dicamba. Analysis of the field samples showed that the maximum residues (total of dicamba and 5-OH dicamba) were 2.14 ppm in forage (Table 1), 0.12 ppm in silage (Table 2) and 0.049 ppm in stover (Table 3). Residues in excess of 0.01 ppm were not observed in any treated grain sample or in any of the nontreated control samples.

Table 1- Field residue data for dicamba on corn forage. Treatment 1- a single preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A; Treatment 2- a preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A plus an early postemergence application of the DMA salt of dicamba at a rate of 0.5 lbs. ai/A; Treatment 3- a preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A plus a mid post emergence application of SAN 1275H at a rate of 0.25 lbs. ai/A; and Treatment 4- a single early postemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A.

State	Crop Age (Days)	Treatment #	Application Volume (gal/A)	Maximum Residue (ppm)		
				Dicamba	5OH-Dicamba	Total
IA	69	1	20	ND	ND	ND
		2	20, 20	ND	ND	ND
		3	20, 20	0.038	0.36	0.40
		4	20	ND	ND	ND
IL	60	1	15	ND	ND	ND
		2	15, 16	ND	0:027	0.027
		3	15, 16	0.018	0.12	0.14
		4	16	0.022	0.16	0.18
IN	60	1	16	ND	ND	ND
		2	16, 17	0.051	0.25	0.30
		3	16, 17	ND	ND	ND
		4	17	ND	ND	ND
KS	61	1	20	ND	ND	ND
		2	20, 20	0.015	0.10	0.12
		3	20, 19	0.44	1.7	2.14
		4	20	0.089	0.79	0.88
NC	59	1	21	ND	ND	ND
		2	21, 20	ND	ND	ND
		3	21, 20	0.093	0.97	1.06
		4	20	ND	0.012	0.012

ND = Not Detected (<0.01 ppm)

Table 2- Field residue data for dicamba on corn silage. Treatment 1- a single preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A; Treatment 2- a preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A plus an early postemergence application of the DMA salt of dicamba at a rate of 0.5 lbs. ai/A; Treatment 3- a preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A plus a mid post emergence application of SAN 1275H at a rate of 0.25 lbs. ai/A; and Treatment 4- a single early postemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A.

State	Crop Age (Days)	Treatment #	Application Volume (gal/A)	Maximum Residue (ppm)		
				Dicamba	5OH-Dicamba	Total
IA	124	1	20	ND	ND	ND
		2	20, 20	ND	ND	ND
		3	20, 20	ND	ND	ND
		4	20	ND	ND	ND
IL	120	1	15	ND	ND	ND
		2	15, 16	ND	ND	ND
		3	15, 16	ND	ND	ND
		4	16	ND	0.017	0.017
IN	123	1	16	ND	ND	ND
		2	16, 17	ND	ND	ND
		3	16, 17	ND	ND	ND
		4	17	0.019	0.026	0.045
KS	142	1	20	ND	ND	ND
		2	20, 20	ND	ND	ND
		3	20, 19	0.015	0.10	0.12
		4	20	ND	0.034	0.034
NC	110	1	21	ND	ND	ND
		2	21, 20	ND	ND	ND
		3	21, 20	0.016	0.066	0.082
		4	20	ND	ND	ND

ND = Not Detected (<0.01 ppm)

Table 3- Field residue data for dicamba on corn fodder (stover). Treatment 1- a single preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A; Treatment 2- a preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A plus an early postemergence application of the DMA salt of dicamba at a rate of 0.5 lbs. ai/A; Treatment 3- a preemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A plus a mid post emergence application of SAN 1275H at a rate of 0.25 lbs. ai/A; and Treatment 4- a single early postemergence application of SAN 1275H at a rate of 1.0 lbs. ai/A.

State	Crop Age (Days)	Treatment #	Application Volume (gal/A)	Maximum Residue (ppm)		
				Dicamba	5OH-Dicamba	Total
IA	159	1	20	ND	ND	ND
		2	20, 20	ND	ND	ND
		3	20, 20	ND	0.014	0.014
		4	20	ND	ND	ND
IL	148	1	15	ND	ND	ND
		2	15, 16	ND	ND	ND
		3	15, 16	ND	ND	ND
		4	16	ND	ND	ND
IN	152	1	16	ND	ND	ND
		2	16, 17	ND	0.019	0.019
		3	16, 17	ND	ND	ND
		4	17	ND	0.012	0.012
KS	154	1	20	ND	ND	ND
		2	20, 20	ND	ND	ND
		3	20, 19	ND	0.049	0.049
		4	20	ND	ND	ND
NC	125	1	21	ND	0.026	0.026
		2	21, 20	0.013	ND	0.013
		3	21, 20	0.034	0.090	0.12
		4	20	0.010	ND	0.010

ND = Not Detected (<0.01 ppm)

CBTS' Conclusions: Over tolerance residues resulting from the use of RH 1275H were reported in corn forage. However, these "forage" samples do not meet the Agencys' definition of forage: "whole aerial portion of the plant at late dough/early dent stage (black

ring stage for corn only" (Table II, June 1994). As now defined, the silage samples are the RAC covered by the forage tolerance. Early season corn forage is not considered to be a significant animal feed item. Thus, all residues in corn RACs in this study were well below the established tolerances of 0.5 ppm. These data are adequate to support this EUP request.

The registration of a new microencapsulated formulation will require a full set of corn field trials, as defined in the "*EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances, 6/2/94.*" For field corn, a total of 20 trials are required, conducted in Region 1- 1 trial, Region 2- 1 trial, Region 5- 17 trials and Region 6- 1 trial. The appropriate modes of application (i.e., preplant, at-plant, preemergence and postemergence) should be represented as detailed in the Field Trial Document. Also, two independent samples from each plot should be collected and analyzed and the minimum spray volume should be represented. The RACs sampled should be forage (as defined in Table II, June 1994), grain and fodder (stover).

Storage Stability Studies

No storage stability data were submitted with this petition.

The maximum storage period for the samples from the field trials was 174 days from sampling to analysis. Previous corn storage stability studies have yielded conflicting results (Dicamba (SSR), Task 2, 5/24/89). An initial study found dicamba to be unstable in corn stalks and grain over a period of 17 months. A later study found dicamba residues to be stable in corn RACs and other commodities for 23-26 months. The registrant reports that a new 3-year storage stability study is in progress. Analysis of the 3-month samples were reported to reveal no evidence of residue decline, but no data were presented. As the samples from the field trials were stored for a relatively short period of time, CBTS concludes that storage stability is not an issue for this EUP. However, for the permanent registration request, further evidence of the storage stability of dicamba and 5-OH dicamba residues in corn RACs will be required. CBTS also notes that some of the samples in this study were stored for up to 1.5 months between extraction and analysis. If the samples for the permanent registration request are stored as extracts, then data demonstrating the stability of dicamba and 5-OH dicamba residues in corn RAC extracts will be required.

cc: Reg. Standard File, S.F., Kramer, circ., R.F.
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